

Package leaflet: information for the user

Cinfadol 11.6 mg/g gel

Diclofenac diethylamine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

1. What Cinfadol is and what it is used for
2. What you need to know before you use Cinfadol
3. How use Cinfadol
4. Possible side effects
5. How to store Cinfadol
6. Contents of the pack and other information

1. What Cinfadol is and what it is used for

Diclofenac diethylamine, the active substance of this medicine, belongs to the group of non-steroidal anti-inflammatory drugs and acts as a painkiller and local anti-inflammatory.

This medicine is indicated for adults and adolescents over the age of 14 years for the local relief of mild and occasional pain and inflammation, caused by:

- Minor contusions, bumps, strains
- Torticollis or other contractures
- Lower back pain
- Mild sprains caused by a twist

2. What you need to know before you use Cinfadol

Do not use Cinfadol

- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6)
- if you have ever suffered an allergic reaction to diclofenac or any other medicine used to treat pain, fever or inflammation such as ibuprofen or acetylsalicylic acid (also used to prevent blood clots). If you are not sure, contact your doctor or pharmacist.
- If you are under the age of 14 years.
- Do not apply to wounds, eczematous lesions, mucous membranes or burns.

If you believe you may be allergic, consult your doctor.

Warnings and precautions

- Do not apply to areas of the skin with cuts or open wounds, the mucous membranes, eczema or rashes.
- Avoid contact with the eyes. If this happens, rinse your eyes with clean water. Consult your doctor or pharmacist if you note any subsequent discomfort.
- Do not use occlusive bandages.
- Do not use on large areas. Use on the affected area only.
- Do not apply simultaneously on the same areas to which other medicines have been applied.
- Do not ingest this medicine or use it in your mouth. It is a medicine for external use only. Consult your doctor or pharmacist in the event of accidental ingestion.
- Do not expose the treated areas to the sun (even when cloudy) or to ultraviolet radiation lamps (UVA rays).

Talk to your doctor or pharmacist before using this medicine.

Children and adolescents

This medicine is not recommended for use in children and adolescents younger than 14 years of age due to the absence of sufficient safety and efficacy data.

Other medicines and Cinfadol

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

During the first six months of pregnancy only use this medicine after consulting your doctor. During the last three months of pregnancy, do not use this medicine, as there is a greater risk of complications for the mother and the newborn.

Breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

You should only use this medicine whilst breast-feeding if advised by your doctor.

Under no circumstances should there be direct application to the breast area.

Driving and using machines

No effect has been reported on the ability to drive vehicles and use machinery when this medicine is used externally on the skin.

Cinfadol contains propylene glycol.

Therefore, this medicine may produce skin irritation.

3. How use Cinfadol

Always use this medicine exactly as described in this leaflet or as your doctor has told you.

This medicine is to be applied to the skin (cutaneous use).

The recommended dose is:

Adults and adolescents over the age of 14 years: Apply a small amount of gel to the inflamed or painful area 3 or 4 times a day.

The amount of gel will vary depending on the size of the affected area (in general, a cherry to walnut sized amount will be sufficient).

Use in children and adolescents

This medicine is not recommended for use in children and adolescents under the age of 14 years due to the absence of sufficient safety and efficacy data.

How to use it:

- The first time you use the tube, unscrew the cap. Insert the rear of the cap into the seal of the tube. Turn the cap to open the tube.
- Spread a fine layer of the gel on the area of the skin that is painful and inflamed, massaging gently.
- Close the tube well after use.
- Wash your hands after applying the gel.

If the pain or swelling gets worse or persists after 7 days of treatment, consult your doctor.

If you use more Cinfadol than you should

If you accidentally swallow Cinfadol or if you have used it on a large area of skin for a long period of time, there may be adverse reactions similar to those produced by diclofenac when taken orally (e.g. tablets).

The main symptoms of overdose are: digestive or renal disorders and shortness of breath.

If you have applied too much gel, we recommend removing it by washing the affected area with abundant water or by physically removing some of the gel.

In case of accidental ingestion go to a medical centre immediately or call the Toxicology Information Service on: 91 562 04 20, indicating the medicine and quantity ingested.

If you forget to use Cinfadol

If you forget to apply this medicine when you should, apply the gel as soon as possible and continue normally with the treatment.

Do not apply a double dose to make up for a forgotten dose.

If you stop using Cinfadol Ibuprofen

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some rare and very rare adverse effects may be severe:

If you experience any of the following signs of allergy, stop using this medicine and consult your doctor or pharmacist immediately.

- Rare: may affect up to 1 in 1,000 people Skin rash accompanied by blistering; urticaria (raised, red wheals, often with an itching and burning sensation).
- Very rare: may affect up to 1 in 10,000 people Shortness of breath or sensation of tightness in the chest (asthma); swelling of the face, lips, tongue or throat.

Non-serious side effects:

Other side effects may occur but they are usually mild and transient. If you notice any of them, consult your doctor or pharmacist as soon as possible.

- Common: may affect up to 1 in 10 people Rash, itching, reddening or burning of the skin after using the product.
- Very rare: may affect up to 1 in 10,000 people The skin may be more sensitive to the sun (photosensitivity). The signs are: sunburn with itching, swelling and blistering.
- Not known: Burning sensation at the application site, dry skin.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Spanish Pharmacovigilance System website: www.notificaram.es/. By reporting side effects you can help provide more information on the safety of this medicine.


5. How to store Cinfadol

Do not store at temperatures above 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Once open, dispose of the tube with the remaining gel after 12 months.

Do not throw away any medicines via wastewater or household waste. Place containers and medicines you no longer use in the SIGRE point  of the pharmacy. Ask your pharmacist how to throw away containers and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cinfadol contains

- The active substance is diclofenac diethylamine. Each gram of gel contains 11.6 mg of diclofenac diethylamine, which corresponds to 10 mg of diclofenac sodium.
- The other ingredients are: propylene glycol, isopropanol, diethylamine, liquid paraffin,

polyoxyethylene alkyl ether, carbomer, coco-caprylate/caprate, perfume, cream 45 and purified water.

What the product looks like and contents of the pack

Cinfadol is packaged in an aluminium tube with a screw cap. The medication is presented in tubes containing 60 g and 100 g of gel.

Marketing licence holder and manufacturer:

Marketing authorisation holder

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10 – Polígono Industrial Areta
31620 Huarte (Navarre) - Spain

Manufacturer

Kern Pharma, S.L.
Polígono Ind.
Colón II C/ Venus 72
08228 Terrassa (Barcelona)
Spain

O

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31620 Huarte (Navarre) - Spain

This leaflet was last revised in: September 2019

Detailed and updated information on this medicine is available on the Spanish Medicines Agency (AEMPS) web site <http://www.aemps.es/>.